510(k) Summary for Dimension Vista™ Protein 1 Calibrator Dimension Vista™ Protein 1 Control L, M and H

AUG - 7 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K062055

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
D-35001
Marburg, Germany

Contact Information:
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: July 18, 2006

2. Device Name:
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H

Classification: Class II; Class I
Product Code: JIX; JJY
Panel: Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dimension Vista™ Protein 1 Calibrator - K061338
Dimension Vista™ Protein 1 Control L- K061338
Dimension Vista™ Protein 1 Control M - K061338
Dimension Vista™ Protein 1 Control H - K061338

4. Device Description:

Dimension Vista™ Protein 1 Calibrator
Protein 1 Calibrator is a multi-analyte, liquid human serum based product containing Immunoglobulin A, Immunoglobulin G and Prealbumin.

Dimension Vista™ Protein 1 Control L, M and H
Protein 1 Control L, M and H are multi-analyte, liquid human serum based products containing Immunoglobulin A, Immunoglobulin G and Prealbumin.

5. Device Intended Use:

Dimension Vista™ Protein 1 Calibrator
Protein Calibrator is an *in vitro* diagnostic product for the calibration of the Immunoglobulin A (IGA), Immunoglobulin G (IGG) and Prealbumin / Transthyretin (PREALB) methods on the Dimension Vista™ System.

Dimension Vista™ Protein 1 Control L, M and H
Protein 1 Control L, M and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of Immunoglobulin A (IGA), Immunoglobulin G (IGG) and Prealbumin / Transthyretin (PREALB) on the Dimension Vista™ System.

6. Medical device to which equivalence is claimed and comparison information:

The Dimension Vista™ Protein 1 Calibrator and Dimension Vista™ Protein 1 Control L, M and H (modified to include prealbumin) are substantially equivalent in intended use to the Dimension Vista™ Protein 1 Calibrator and Dimension Vista™ Protein 1 Control L, M and H (K061338).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kathleen Dray-Lyons
Manager, Regulatory Affairs and Compliance
Dade Behring, Inc.
Glasgow Site
PO Box 6101, M/S 514
Newark, DE 19714-6101

AUG - 7 2006

Re: k062055
Trade/Device Name: Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX, JJY
Dated: July 18, 2006
Received: July 20, 2006

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications Statement

K062055

Device Name: **Dimension Vista™ Protein 1 Calibrator**
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H

Indications for Use:

Dimension Vista™ Protein 1 Calibrator
Protein 1 Calibrator is an *in vitro* diagnostic product for the calibration of the Immunoglobulin A (IGA), Immunoglobulin G (IGG) and Prealbumin / Transthyretin (PREALB) methods on the Dimension Vista™ System.

Dimension Vista™ Protein 1 Control L, M and H
Protein 1 Control L, M and H are for use as assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of Immunoglobulin A (IGA), Immunoglobulin G (IGG) and Prealbumin / Transthyretin (PREALB) on the Dimension Vista™ System.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062055